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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,484	07/08/2003	Alan R. Fritzberg	295.034US1	8966

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/615,484

Applicant(s)

FRITZBERG, ALAN R.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 4/14/05; 8/2/04; and 1/31/05.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-58 and 60-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-58 and 61-63 is/are allowed.
- 6) ☒ Claim(s) 60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/14/05; 8/2/05; & 1/31/05 08/02/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 1/31/05 wherein claim 59 was canceled; claims 60 and 61 were amended; and claim 63 was added.

**Note:** Claims 1-58 and 60-63 are pending.

## RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments filed 1/31/05 to the rejection of claims 59 and 60 made by the Examiner under 35 USC 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

### **112 Rejections**

I. The 112, second paragraph, rejections of claims 59 and 60 (in part) are WITHDRAWN because Applicant has amended and/or canceled the claim.

II. The rejection of claim 60 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 7/27/04 and those set forth below.

Applicant asserts that the phrase 'condition treatable with stem cell transplantation, with and without gene therapy' is definite because one of skill in the art would understand the scope of the invention in light of the specification.

Applicant's argument is not persuasive because the phrase 'condition treatable with stem cell transplantation, with and without gene therapy' does not set forth what

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condition Applicant is referring to that is compatible with the instant invention. In the specification, see paragraph [0039], pages 2-3 of the PG Pub. document (US 2004/0096393), sickle cell anemia and lysosomal and peroxisomal storage diseases are disclosed. Thus, it is unclear what other conditions Applicant is referring claim are treatable. Furthermore, it is unclear when and if a condition encompassed by Applicant's invention requires gene therapy since it is unclear what conditions are of interest.

## **NEW GROUNDS OF REJECTION**

### **112 First Paragraph Rejection**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 60 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for conditions treatable with stem cell transplantation, with or without gene therapy, that utilize bone marrow ablation such as sickle cell anemia and lysosomal and peroxisomal storage diseases, does not reasonably provide enablement for all conditions treatable with stem cell transplantation, with or without gene therapy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claim is directed to a therapeutic method of treating a condition treatable with stem cell transplantation, with or without gene therapy, that utilize bone marrow ablation.

(2) State of the prior art

The references of record do not indicate which specific conditions treatable with stem cell transplantation, with or without gene therapy, that utilize bone marrow ablation are useful with the claimed invention.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Dependent claim 60 encompasses a vast number of possible conditions. Applicant's specification does not enable the public to use the complexes of claim 52 for such a vast number of conditions.

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(4) Level of predictability in the art

The art pertaining to the stem cell transplantation, with and without gene therapy is highly unpredictable. Determining the various types of conditions or class of conditions treatable with stem cell transplantation, with or without gene therapy, that utilize bone marrow ablation requires various experimental procedures and without guidance that is applicable to all conditions, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

Dependent claim 60 encompasses a vast number of conditions. Applicant's limited guidance does not enable the public to treat such a numerous amount of conditions. There is no directional guidance for the conditions treatable with stem cell transplantation, with or without gene therapy, that utilize bone marrow ablation, except sickle cell anemia and lysosomal and peroxisomal storage diseases (see pages 2-3 of US 2004/0096393 (Applicant's PG Pub. Document), paragraph [0039]). Hence, there is no enablement for all possible conditions treatable with stem cell transplantation.

(6) Existence of working examples

Dependent claim 60 encompasses a vast number of conditions. Applicant's limited working examples do not enable the public to treat such a numerous amount of conditions treatable with stem cell transplantation, with or without gene therapy, that utilize bone marrow. While Applicant's claims encompass a plethora of possible conditions, the specification provides only for conditions such as sickle cell anemia and lysosomal and peroxisomal storage diseases.

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(7) Breadth of claims

The claims are extremely broad due to the vast number of possible conditions treatable with stem cell transplantation with and without gene therapy known to exist.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

## **ALLOWABLE CLAIMS**


5. Claims 1-58 and 61-63 are allowable over the prior art of record for reasons of record in the office action mailed 7/24/04.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
Art Unit 1616

May 13, 2005